

## **REMARKS**

In the specification, paragraphs [0026] on page 8, [0037] on pages 10-11, [0056] on pages 15-16 of the specification as filed are amended to identify SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:7, respectively.

Claims 1, 14, 28 and 47 are amended to recite a full length complement of a specified sequence, conditions of hybridization stringency, and to delete percent sequence identity. Support for these amendments can be found throughout the specification as filed, including, for example, at paragraph [0143] on page 37. The term "monocotyledonous" is deleted from Claim 19, and the term "renders" recited in Claim 22 is replaced with the term "confers". No new matter has been added. Claims 1-9, 14-33, 35, and 47 remain pending.

Applicant has carefully considered all of the Examiner's rejections and respectfully submits that the claims are allowable for at least the following reasons.

### **Claim Objections**

Applicant respectfully submits that the Examiner's objections to Claims 19 and 22 are moot where the term "monocotyledonous" in Claim 19 has been deleted, and the term "renders" in Claim 22 has been replaced with the term "confers."

### **Information Disclosure Statement**

Applicant submits an information disclosure statement herewith containing references listed in the application.

### **Rejection under 35 U.S.C. § 112 (Enablement)**

The Examiner rejects Claims 1-9, 14-35 and 47, contending that while the specification is enabling for an isolated polynucleotide encoding SEQ ID NO: 2 or 4, the specification does not reasonably enable an isolated polynucleotide having less than 100% sequence identity to SEQ ID NO: 1 or 3. The Examiner asserts that the state of the prior art teaches that not all nucleotide sequences that hybridize to each other will encode proteins of similar function, even if the hybridization conditions are relatively high stringency. To support this provision, it is alleged

that Broun *et al.*, (1998, *Science*, 282: 1315-1317) teach as few as four amino acid substitutions in a protein can change the protein activity (abstract) and that the nucleic acid sequences encoding such proteins would hybridize to each other under high stringency conditions. On this basis, the Examiner opines that it would be unpredictable as to whether any and all nucleotide sequences that hybridize to SEQ ID NO: 1 or 3 under high stringency conditions would encode a protein with the desired functional activity. The Examiner also asserts that while fungal disease resistance activity of SEQ ID NO: 1 or 3 encoding SEQ ID NO: 2 or 4 is an inherent property, the ability of the sequence to induce fungal disease resistance activity cannot be extrapolated to sequences having less than 100% sequence identity and to other diseases, absent specific guidance.

Applicant respectfully disagrees because the specification clearly provides direction for selecting an isolated polynucleotide that encodes a polypeptide conferring fusarium resistance to a plant, or to a full length complement of the nucleotide sequence, wherein the nucleotide sequence is selected from SEQ ID NO: 1 or 3, for example, at pages 36 to 40.

Paragraphs [0141]-[0142] on page 36 of the specification as filed state that the nucleic acid variants of the invention can be naturally occurring or can be made by mutagenesis techniques. The variants can contain nucleotide substitutions, deletions, inversions and insertions. Conservative variants include those sequences that, because of the degeneracy of the genetic code, encode the amino acid sequence of one of the R polypeptides of the invention. In addition, the specification describes isolation and cloning of the nucleic acid sequences of SEQ ID NO: 1 and 3 from *Musa acuminata* spp and prophetic methods for transforming plants.

Applicant draws the Examiner's attention to the nucleotide sequences of two R genes (RGA5 (SEQ ID NO: 1) and RGA2 (SEQ ID NO: 3)) disclosed in the specification that share less than 90% sequence identity and encode proteins which confer disease resistance to fusarium. A skilled artisan wishing to identify a sequence that would hybridize to SEQ ID NO: 1 or 3 under high stringency conditions would be capable of making codon substitutions in the disclosed sequences that would result in "synonymous" polynucleotides (*i.e.*, ones that encode the same amino acid sequence). Thus a person skilled in the art could make numerous synonymous variants of SEQ ID NO: 1 or 3 by taking advantage of the degeneracy of the genetic code, and these sequences would hybridize to SEQ ID NO: 1 and 3 under high stringency conditions. The

resulting fusarium resistance could then be tested. Additionally, a skilled artisan wishing to identify polypeptide sequences with fusarium resistance could consult the formulas within the specification (see paragraphs [0026]-[0036]; [0037]-[0055]; and [0056]-[0075]) which provide clear directions for selecting specific amino acid residues to produce a related polypeptide sequence which again could be subsequently tested for fusarium resistance.

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. Applicant submits that for a claimed genus, representative examples together with a statement applicable to the genus as a whole will be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation (e.g., M.P.E.P. 2164.02).

In light of the above, Applicant submits that the features of the claimed invention offer sufficient guidance to the skilled artisan to make and use the instant invention using only routine and art-recognized techniques. More particularly, in view of the specification, and further in view of the level of general knowledge in this art, the skilled artisan would readily understand how to identify, make and use sequences that would hybridize under high stringency conditions to a full length complement of the sequence set forth in SEQ ID NO: 1 or 3 and to evaluate whether such sequences would be capable of conferring fusarium resistance to a plant.

To expedite favorable prosecution, the percentage sequence identity language has been deleted from the claims and high stringency conditions, described at page 37, paragraph [0143] of the specification, have been inserted. Reconsideration and withdrawal of the rejection are respectfully requested.

**Rejection under 35 U.S.C. § 112 (Written Description)**

The Examiner rejects Claims 1-9, 14-35 and 47 as failing to comply with the written description requirement. The Examiner states that the claims are broadly drawn to a multitude of sequences having 95% sequence identity to SEQ ID NO: 1-2 or 3-4, complementary sequences thereof, and nucleic acid sequences that hybridize to SEQ ID NO: 1 or 3 under unspecified high stringency conditions, wherein the nucleic acids confer disease resistance to plants. In contrast, the Examiner asserts that the specification describes isolation and cloning of the nucleic acid

sequences of SEQ ID NO: 1 and 3 from *Musa acuminata* and prophetic methods of transforming plants with said nucleic acid sequences. Furthermore, the Examiner alleges that the Applicant has not described the composition or structure of all the nucleotide sequences as broadly claimed and has not described a representative number of nucleotide sequences of the genus of the claims.

Applicant respectfully traverses this ground of rejection. In particular, the USPTO has specifically indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an Applicant discloses functional and/or descriptive information concerning the specie(s) in an application, e.g., a distinguishing identifying characteristic common among the members of a claimed genus (see *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para 1, "Written Description" Requirement* - Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111). For example, at the bottom of page 1105, the *Guidelines* state that, "an adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention."

Applicant strenuously disagrees with the contention that it was only in possession of the specific sequence of SEQ ID NO: 1 and 3 (encoding SEQ ID NO: 2 and 4) at the time this application was filed. Moreover, Applicant submits that to accept such a position would result in the exclusion of an entire class of sequences related to SEQ ID NO: 1 and 3 that are useful in the context of the Applicant's invention, despite the fact that the skilled artisan would absolutely recognize the value of sequences related to SEQ ID NO: 1 and 3 in the context of the Applicant's disclosure.

Accordingly, Applicant believes that the present disclosure more than adequately establishes possession of the currently claimed invention. In particular, the Applicant has disclosed the detailed structure of the R gene families RGA2 and RGA5, e.g., SEQ ID NO: 1 and 3, and has also identified these sequences as having resistance to fusarium. Thus, in the context of the presently claimed invention, the skilled artisan would recognize that the fusarium resistance of SEQ ID NO: 1 and 3 represents a distinguishing identifying characteristic common among the polynucleotides of the claimed invention.

Further still, in view of this identifying characteristic, the skilled artisan would immediately recognize that the Applicant was in possession of much more than the specifically recited species of SEQ ID NO: 1 and 3. In view of the fusarium resistance identified by the Applicant for this sequence, the skilled artisan would undoubtedly understand and expect that a multitude of sequences structurally related to SEQ ID NO: 1 and 3, *e.g.*, sequences that encode a polypeptide conferring fusarium resistance to a plant, or a full length complement of SEQ ID NO: 1 and 3, would be useful in the same capacity as the specific species of SEQ ID NO: 1 and 3.

Moreover, by the addition of the phrase "fusarium resistance" to the claims, Applicant has specifically incorporated this illustrative identifying characteristic into the claims under consideration, such that a polynucleotide of the invention is one that encodes a polypeptide conferring fusarium resistance to a plant. Accordingly, in view of the Applicant's identifying characteristic disclosed for SEQ ID NO: 1 and 3, Applicant respectfully submits that the skilled artisan would appreciate that the applicant was in clear possession of a genus of sequences related to SEQ ID NO: 1 and 3 similarly conferring fusarium resistance to a plant. Applicant thus submits that the instant claims fully comply with the written description requirements of 35 U.S.C. § 112 and reconsideration of the Examiner's rejection is respectfully requested.

**Rejection under 35 U.S.C. § 102**

The Examiner rejects Claims 1 and 47 as anticipated by Gimenez *et al.*, (AF529036, deposited 16 July 2002, Applicant's IDS). The Examiner alleges that Gimenez *et al.*, teach an isolated polynucleotide from *Musa acuminata* which comprises a complement of SEQ ID NO: 1 or 3 of the instant application or a complement of a nucleotide sequence encoding SEQ ID NO: 2 or 4 of the instant application. The Examiner alleges that the prior art nucleic acid sequence will also hybridize to SEQ ID NO: 1 or 3 of the instant application under high stringency conditions and as such, Gimenez *et al.* allegedly anticipate the claimed invention.

Applicant respectfully traverses this rejection and submits that it is well established that a reference only anticipates a claim if it discloses each and every element of that claim (*e.g.*, M.P.E.P. 706.02). Moreover, anticipation requires that the identical invention must be shown in

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as complete detail as is contained in the claim (Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Applicant submits that Gimenez *et al.* neither teaches nor suggests an association between the disclosed sequences and fusarium resistance. The Gimenez *et al.* sequence is 336 nucleotides in length and the corresponding polypeptide sequence comprises 167 amino acids. The D1 nucleotide sequence submitted to the EMBL database on 16 July 2002 was derived from genomic DNA which is not shown to encode an active protein with fusarium resistance or any other disease resistance. By contrast, the protein encoded by SEQ ID NO: 1 of the instant application is 1441 amino acids in length and confers fusarium resistance to a plant as recited in the pending claims.

It is also the case that Gimenez *et al.* neither teaches nor suggests that the isolated polynucleotide from *Musa acuminata* would hybridize to SEQ ID NO: 1 or 3 under the high stringency conditions recited in the claims. Applicant respectfully requests reconsideration and withdrawal of this rejection.

#### **Rejection under 35 U.S. C. § 101**

The Examiner rejects Claim 47, alleging that the claim reads on a polynucleotide in its natural source. Applicant respectfully submits that the rejection is obviated where Claim 47 has been amended to recite an "isolated" polynucleotide.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

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reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

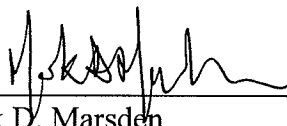
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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